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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,835	06/23/2005	Kohji Kawahara	4007561-173515	2192
23570 7590 01/19/2011 PORTER WRIGHT MORRIS & ARTHUR, LLP INTELLECTUAL PROPERTY GROUP 41 SOUTH HIGH STREET 28TH FLOOR COLUMBUS, OH 43215				
EXAMINER HUANG, GIGI GEORGIANA				
ART UNIT		PAPER NUMBER		
1617				
MAIL DATE		DELIVERY MODE		
01/19/2011		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/540,835

Applicant(s)

KAWAHARA ET AL.

Examiner

GIGI HUANG

Art Unit

1617

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 8-15 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6, 8-15 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/30/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. The response filed October 22, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:
 - a. Claim 21 has been amended.
2. Claims 2-6, 8-15, 21-23 are pending in the case.
3. Claims 2-6, 8-15, 21-23 are present for examination.
4. Due to amendment of the claims, all grounds not addressed in the action are withdrawn or moot.
5. New grounds of rejection are set forth in the current office action.

Information Disclosure Statement

6. The information disclosure statement filed 9/30/2010 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. JP 8-509202 is not a complete or legible copy as the majority of the pages are blank. It has been placed in the application file, but the information referred to therein has not been considered.

New Grounds of Rejection

Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2-6, 8-15, 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are unclear to the recited subject matter. The independent claim recites the presence of a group of conditions consisting of "ocular infection of conjunctiva, lacrimal tissue and cornea, allergic conjunctivitis, pollinois, vernal conjunctivitis, conjunctivitis, blepharitis, keratitis, corneal tumor, dacryocystitis, superficial dermatitis, marginal blepharitis, scleritis, holdeolum tarsadentitis, and trachoma" wherein it is unclear how there can be an ocular infection of allergic conjunctivitis, vernal conjunctivitis, keratitis, etc., as written. For purposes of examination, the conditions to be an ocular infection of conjunctiva, lacrimal tissue and cornea; allergic conjunctivitis; pollinois; vernal conjunctivitis; conjunctivitis; blepharitis; keratitis; corneal tumor; dacryocystitis; superficial dermatitis; marginal blepharitis; scleritis; holdeolum; tarsadentitis; and trachoma.

8. Claims 5-6 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 as written is unclear as it recites the remedy for the ophthalmic disease to be ketotifen fumarate or diclofenac sodium for a patient population with disease conditions including infection of at least one of the anterior tissue of the eye and to be effective for the condition, wherein it is unclear how these two drugs are effective for the different conditions present in the independent claim as the art only supports for its

effectiveness for only some the recited conditions and issues of enablement for the breath of the drugs for the conditions may arise. Clarification and correction is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2-5, 8-15, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tojo et al. (WO 01/26648) in view of Patel et al. (Ocular manifestations of Autoimmune Disease).

It is noted that U.S. Pat. 7052714 will be used as the translation for WO 01/26648 and all references are to the U.S. Patent.

It is also noted that the claims as written, are reciting a method for percutaneously transferring a remedy (drug) for ophthalmic diseases to an ophthalmic topical tissue comprising applying a transdermal drug delivery system comprising a plaster and a support, to the skin surface of an eyelid to a patient population having certain conditions, rather than a method of treating the conditions with the administration of the drug (remedy) with a transdermal patch as it appears to attempt to amend toward. However, transfer of the drug intrinsically occurs when a composition with the recited components (such as transdermal formulation) is applied to the cited mode of administration (applied to the skin of an eyelid). In fact, drug transfer is intrinsic

to transdermal formulations by the nature of the art.

Tojo et al. teaches the use of transdermal preparations for the delivery of ophthalmic agents for conditions of the posterior eye such as intrinsic uveitis. The transdermal preparations comprise an adhesive with a drug (plaster) with a release membrane, and a lining film (support). Drugs taught include corticosteroids (e.g. prednisolone) which are anti-inflammatories/antiallergics well known in the art to be useful for many conditions including conjunctivitis and uveitis (evidenced by Becker et al.).

The intrinsic uveitis caused by autoimmune mechanism or abnormal immune response (autoimmune disease) taught by Tojo includes known autoimmune conditions such as systemic lupus erythematosus and psoriatic arthritis, which presents with other ocular manifestations such as conjunctivitis, keratitis, and scleritis wherein the recited patient population is encompassed as addressed by Patel et al. (Table 1) where the same patient populations are intrinsically present and are implicitly treated, or alternatively obvious for treatment when encompassing the same population. The patch comprises percutaneous absorption enhancer including polyoxyethylene oleyl ether, fatty acids, fatty acid esters, and higher alcohols at 5-30w/w.%; adhesives including acrylics (e.g. Nippon Carbide Industries PE-300, an alkyl (meth)acrylate-vinyl acetate copolymer), silicone base, or rubber base (e.g. styrene-isoprene-styrene copolymer) at 1-20wt.% and tackifier (e.g. thickeners, coagulation enhancers, paraffin); and the drug at 1-20wt.% which can be adjusted as desired based on the disease to be treated and its severity.

The patch can be applied to any desired body surface including the eyelid (see full document, specifically, Abstract, Col. 2 line 10-68, Col. 5 line 27-col. 7 line 40, col. 13 line 55- Col. 15 line 20, claim 7-10, 13-14, 16). Examples are presented where the general teaching for the patches has the components such as the acrylic, the enhancer, and the drug meets the claims. Example 2, 3, and 5 have the acrylic at 5.0 g (100parts, thereby 1 part is 0.05g), the enhancer is at 0.6g (12 parts), the drug is at 0.3g (6 parts-Ex.2), 0.45g (9 parts-Ex.3), and 0.3g (6 parts-Ex.5). General teaching in Example 11 for the styrene-isoprene-styrene (SIS) patches have the SIS at 0.9g (100parts, thereby 1 part is 0.009g), the isopropyl myristate enhancer is at 0.3g (33.3 parts), and the drug is at 0.15g (16.6 parts), the paraffin (tackifier) is at 0.15g (16.6 parts) meeting the claims. As for the permeation recitations, the effects of applying the composition (e.g. the amount of transfer and penetration) are intrinsic to the components of the composition and the mode of delivery. When the composition is delivered in the same manner as claimed, the effects of the composition would be the same such as penetration and the therapeutic profile, as they are a direct result of the components of the composition and the mode of administration which are met by the art whereby the resulting properties and effects would intrinsically be met as any component that materially affects the composition and its properties would have to be present in the claim to be commensurate in scope.

As the application of the patch as taught in Tojo would intrinsically treat patients who may have the conditions recited as addressed by Patel et al. above, and has an inclusion/overlap of patient populations of the art and the claimed conditions, where the

drugs must pass through the eye (from anterior to posterior) as seen in Tojo (Table 8- drug present in other ocular tissues including the cornea and the sclera), and that the claims are not a method of treatment, but a method of percutaneously transferring a drug from the patch to the skin to tissue which as addressed above, is intrinsic to the application of transdermal devices by the nature of the art.

Response to Arguments:

Applicant's arguments are moot in view of the new rejection as a result of the claim amendments. It is noted however, that Applicant's assertion that there is no teaching by Tojo of the percutaneous transfer of a remedy to the external ophthalmic tissue. In fact Tojo teaches in Table 8, that the drug percutaneous transfer occurred not only in the posterior portion of the eye but was also present in other ocular tissues including the cornea and the sclera, where there is intrinsically the percutaneous transfer of the remedy as known in the art from the patch through the skin into the eye to the target tissues-the anterior and the posterior (intraocular) portion of the eye. As a result, the transfer intrinsically occurs once the composition is placed in the area recited as the drug concentration and resulting effects are intrinsic to the components of the composition and the mode of delivery which are met by the art whereby the resulting properties and effects would intrinsically be met as any component that materially affects the composition and its properties would have to be present in the claim to be commensurate in scope. It is also known in the art that percutaneous permeation is simply the transfer of the drug through the skin which is still required as known in the art to reach any tissue beneath the skin (blood vessel, ocular tissue, vitreous) and is an

intrinsic property of any transdermal patch. It is also noted that several of the arguments appeared to be centered on a method of treatment where as addressed above, the claims are not currently written as a method of treatment with the application of the patch, but a method of percutaneously transferring a remedy which is intrinsic to all patches, to a patient population with certain disease conditions.

10. Claims 5-6 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tojo et al. (WO 01/26648) in view of Patel et al. (Ocular manifestations of Autoimmune Disease) as applied to claims 2-5, 8-15, 21-23 above, and further in view of Takeuchi et al. (US 5929115).

The teachings of Tojo in view of Patel are addressed above.

Tojo in view of Patel does not expressly address the use of ketotifen or diclofenac sodium, but does teach the treatment of ocular manifestations of autoimmune diseases such as uveitis, keratitis, and conjunctivitis; with certain drug classes like steroids and NSAIDS (nonsteroidal antiinflammatories, e.g. keratitis).

Takeuchi et al. teaches that diclofenac sodium (DFNa, a known NSAIDS) is effective for the treatment of endogenous uveitis (e.g. uveitis from lupus), conjunctivitis, and keratitis (Col. 3 line 21-34, Col. 17 line 34-Col.18 line 2).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use diclofenac sodium, as suggested by Takeuchi, and produce the instant invention as it is *prima facie* obvious to use a NSAID such as diclofenac sodium which is effective for the conditions addressed including uveitis, conjunctivitis, and keratitis, with a reasonable expectation of success.

One of ordinary skill in the art would have been motivated to do this because it is desirable to use a NSAID drug that can treat and is effective for the target ocular condition.

11. Claims 2-6, 8-15, 21-23 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Higo et al. (U.S. Pat. 5866157) in view of Trimming et al. (U.S. Pat. Pub. 2001/0006968) in view of Tojo et al. (WO 01/26648) in view of Lerner et al. (WO 97/18855).

It is noted that U.S. Pat. 7052714 will be used as the translation for WO 01/26648 and all references are to the U.S. Patent.

Higo et al. teaches the use of a transdermal patch which has increased percutaneous absorbability of the drug and reduced irritation to the skin for the administration of active agents including ketotifen taught as a known antiallergic, with a reservoir and a support. Higo also teaches the patch to have an absorption enhancer, a hydrophobic high molecular material (adhesive), a tackifying resin, other components. The amount of active (e.g. ketotifen) is 0.1 to 20%, hydrophobic high molecular material is 15 to 65%, the tackifier is 10 to 70%, and the absorption enhancer is from 0.01 to 20%. The hydrophobic high molecular material can comprise styrene-isoprene-styrene block copolymers, isoprene rubber, and acrylic polymers such as copolymer of methacrylate, acrylic acid, and vinyl acetate. The absorption enhancer can comprise C6-C20 fatty acids, fatty alcohols, fatty acid esters or ethers, and other materials (see full document). There are examples of ketotifen matrix patches on a support (backing) wherein the amount of the components meet the claims such as Example 1: styrene-

isoprene-styrene at 16.5% for Example 1 (100 parts/16.5g, 1 part=0.165g), tackifier-Alicyclic saturated hydrocarbon resin at 29.5% (178.8 parts), and ketotifen fumarate at 2% (12.1 parts); and Example 7: styrene-isoprene-styrene at 36.5% for Example 1 (100 parts/36.5g, 1 part=0.365g), tackifier-Alicyclic saturated hydrocarbon resin at 10% (27.4 parts), and ketotifen fumarate at 3.5% (9.59 parts)

Higo does not expressly teach an example with an acrylic polymer in the amounts claimed. Higo does teach that the hydrophobic high molecular material can comprise styrene-isoprene-styrene block copolymers, isoprene rubber, and acrylic polymers such as copolymer of methacrylate, acrylic acid, and vinyl acetate whereby these materials are taught to be functional equivalents. Higo also teaches that ketotifen is a known antiallergic with examples.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the acrylic polymer for the styrene-isoprene-styrene block copolymers in the ketotifen examples presented as Higo teaches that these hydrophobic high molecular materials are functional equivalents. It is desirable for manufacturers to have analogous choices to substitute the hydrophobic high molecular material when motivated by pricing, availability, or desired properties of the polymer such as the degree of adhesiveness, for the production of the final product.

Higo does not expressly teach placement on the eyelid for the patient population with the recited conditions. Higo does teach that ketotifen is a known antiallergic.

Trimming et al. teaches that ketotifen (e.g. ketotifen fumarate) is useful for the treatment of allergic conjunctivitis, such as seasonal allergic conjunctivitis (see full document).

Tojo teaches that transdermal patches for ophthalmic conditions are known and can be applied to any body surface including the eyelid and also transfers to the anterior tissue (Table 8-drug present in other ocular tissues including the cornea and the sclera, Col. 7 line 35-40).

Lerner teaches that the skin of the eyelid has a resistance lower than that on the rest of the skin surface (Page 37 line 38- Page 38 line 1).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the ketotifen patch on the eyelid for its known use in treating those with the condition, as suggested by Trimming, Tojo, and Lerner, and produce the instant invention. It would have been obvious to one of skill in the art as ketotifen is known in the art to be used for allergic conditions including allergic conjunctivitis and transdermal patches are known to provide safe continuous delivery as addressed by Higo, it would be *prima facie* obvious to use the transdermal patch for allergic conjunctivitis and place the patch as close to the eye as ocular transdermal patches are known as addressed by Tojo, and as it is taught by Lerner that the skin surface over the eyelid has less resistance than the rest of the skin of the body to provide not only direct deliver but more effective delivery as there is better penetration from the lower resistance also providing motivation (improved delivery-lower resistance) for one of skill in the art to do so. It is also *prima facie* obvious that when treating for

allergic conjunctivitis, that the patient has the condition to require treatment as it is desirable to address the eye condition when present.

One of ordinary skill in the art would have been motivated to do this because it is desirable to provide better delivery of a known composition for a known treatment with a known method of administration with greater efficacy due to the lowered resistance of the eyelid. As for the recited permeation, when the composition is delivered in the same manner as claimed, the effects of the composition would be the same such as penetration and the therapeutic profile, as they are a direct result of the components of the composition and the mode of administration which are met by the art whereby the resulting properties and effects would intrinsically be met as any component that materially affects the composition and its properties would have to be present in the claim to be commensurate in scope.

It is noted that the percutaneous transfer of a remedy (drug) intrinsically occurs when a composition with the recited components (such as transdermal formulation) is applied to the cited mode of administration (applied to the skin of an eyelid). In fact, drug transfer is intrinsic to transdermal formulations by the nature of the art. The claims are not a method of treatment but a method of transferring a drug from the patch to the skin to tissue which as addressed above is intrinsic to the application of transdermal devices by the nature of the art.

Response to Arguments:

Applicant's arguments filed 10/22/2010 are fully considered but are not persuasive. Applicant's arguments are centered on addressing the references

individually rather than the combination. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In regards to the argument that Higo is to systemic delivery, Trimming is to eye drops, Tojo is to the posterior eye, and Lerner to iontophoresis- this is not persuasive as the references are taken individually and not in context of the rejection. Higo is designed to show that drug delivery with a transdermal patch with conventionally known materials are known such as ketotifen and Trimming addresses that ketotifen is known for treating allergic conjunctivitis, such as seasonal allergic conjunctivitis, where it is prima facie obvious to use a patch with ketotifen for its known use such as allergic conjunctivitis, and transdermal patches for ophthalmic conditions are known and can be applied to the eyelid as addressed by Tojo which also addresses that percutaneous transfer also occurs to the anterior portion of the eye, which is desirable as Lerner teaches it is known that the skin of the eyelid has a resistance lower than that on the rest of the skin surface (easier to get through the skin at the eyelid) where there is a reasonable expectation of success. It is noted that Lerner is merely used for only a specific section, contrary to Applicant's argument, and the area utilized (Page 37 line 38- Page 38 line 1) is merely used to show that it is known in the art that the skin around the eye has less resistance (easier to penetrate).

Applicant's arguments are also centered on the assertion of the amount of drug transferred to the external ophthalmic tissue verses systemic delivery. This is fully

considered but not persuasive as drug transfer intrinsically occurs once the composition is placed in the area recited as the drug concentration and resulting effects are intrinsic to the components of the composition and the mode of delivery which are met by the art references whereby the resulting properties and effects would intrinsically be met as any component that materially affects the composition and its properties would have to be present in the claim to be commensurate in scope. The whole basis for the transdermal art is the application of a patch with components on the skin at a particular area of the body. It is also known in the art that percutaneous permeation is simply the transfer of the drug through the skin which is still required as known in the art to reach any tissue beneath the skin (blood vessel, ocular tissue, vitreous) and is an intrinsic property of any transdermal patch as once you place the patch in the desired area, the resulting drug delivery is dependent on the patch composition. It is also noted that several of the arguments appeared to be centered on a method of treatment where as addressed above, the claims are not currently written as a method of treatment with the application of the patch, but a method of percutaneously transferring a remedy which is intrinsic to all patches, to a patient population with certain disease conditions.

Accordingly, the rejection is maintained.

Double Patenting

12. Claims 2-5, 8-15, 21-23 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-7, 11, 48 of copending Application No. 10/569772 in view of Tojo et al. (WO 01/26648).

The claims of the conflicting application are drawn to the application of a muscarinic receptor agonist in a base matrix (acrylic, silicone, rubber adhesive) to the skin surface of the eyelid to promote lacrimal fluid secretion (percutaneous transfer of the remedy) which is known to be useful for keratoconjunctivitis (addressing the ocular condition and patient population), a form of allergic conjunctivitis (see Wong et al.- Abstract) and would intrinsically treat the condition.

The conflicting claims do not recite a support. However, as taught by Tojo et al. it is obvious to add a support (lining film) to the base matrix as part of a transdermal delivery system to improve adhesion. As a result, the instant claim is obvious over the copending claims and encompasses the specific conflicting claims.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments:

Applicant's arguments filed 10/22/2010 have been fully considered but they are not persuasive. Applicant's arguments are centered on the assertion that the methods are distinct therapies. This is not persuasive as the instant claim is not directed to that therapy as addressed in the art rejections above, but to the intrinsic property of the drug transfer of the patch to the target tissue to a patient population with certain ophthalmic conditions. This is not the same as a method of treatment/therapy, however it would be obvious for the use of a patch applied to the skin surface of the eyelid containing a drug that is effective for promoting lacrimal secretion known to be useful for known conditions like allergic conjunctivitis for those with the condition wherein the patch intrinsically transfers the remedy upon application to the eye.

Accordingly, the rejection is maintained.

Conclusion

13. Claims 2-6, 8-15, 21-23 are rejected.
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, FEREDOUN SAJJADI can be reached on 571-272-3311. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GiGi Huang/
Examiner, Art Unit 1617
/Zohreh A Fay/
Primary Examiner, Art Unit 1627